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Amendments to the Drawings

Figs 5 and 6 have been corrected in response to the Examiner's objections, to show the proper abbreviation for micromolar. Figs. 5 and 6 now read "μM" instead of "mM."

In addition, applicants have corrected Figs. 7, 8, 9, 10, & 11, which also contain the same error. These figures now read "μM" instead of "mM."

Applicants have also amended Figs. 5, 6, 7, 8, 9, 10, and 11 to refer to "0.023", "0.011", and "0.045" instead of "023", ".011", and ".045", respectively to add a "0" in the ones column for clarity and ease of reading.

Applicants have amended the title of Fig. 7 to change "clotting speed" to "clotting time." Fig. 12 has also been amended to add a label to the Y axis of "Clotting Time (Sec)", which was inadvertently omitted in the submission of formal drawings.

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Remarks/Arguments

The Office Action mailed on April 25, 2005 has been received, its contents carefully noted, and the applied citations thoroughly studied. Accordingly, the foregoing revisions to the claims are tendered with the conviction that patentable contrast has now been made manifest over the known prior art. All rejections tendered by the Examiner in the above-referenced Office Action are hereby respectfully traversed and reconsideration is respectfully requested.

I. Informalities

The Examiner has objected to the amendments made on February 14, 2005 to two sentences on page 16 of the specification (in the description of Fig. 6) concerning the concentrations of calcium chloride in micromolar and millimolar units on the grounds that applicants' remarks were unclear. (Office Action, page 3, paragraph 6.)

Applicants have now amended these two sentences to read exactly as they were originally written in the specification, except that the units "μm" were corrected to read "μM" in the amendment of February 14, 2005, and the numbers have been rewritten in this amendment to add a zero to the ones column for clarity and ease of reading. These sentences now read: "As shown, the thrombin life span where the calcium chloride concentration is at 0.023μM of 250mM calcium chloride appears optimized and extends to 360 minutes while maintaining a clot time under 5 seconds. The range between 0.011μM of 125mM and 0.045μM of 500mM, however, has utility." These statements are supported by the specification in that the legend of figure 6 as originally filed refers to "Concentrations in Final Volume - .011μM of 125mM $CaCl_2$, .023μM of 250mM $CaCl_2$, and .045μM of 500mM $CaCl_2$." Thus, the specification as originally written was supported.

The Examiner has objected to Figs. 5 and 6 on the grounds that they refer to the concentration of calcium chloride in units of "μm" which is an incorrect abbreviation for micromolar (μM). (Office Action, page 3, paragraph 6). Applicants appreciate the Examiner's notation of this error. Applicants have corrected Figs. 5 and 6 to read "μM"

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and have also corrected Figs. 7, 8, 9, 10, and 11, which contain the same error. Applicants have submitted marked-up versions of Figs. 5, 6, 7, 8, 9, 10, and 11 showing these corrections for the Examiner's review and approval. If approved, applicants will submit corrected formal drawings of these figures.

Applicants have also amended the specification (at pages 11, 14, 16, and 17) and the drawings (at Figs. 5, 6, 7, 8, 9, 10, and 11) to refer to "0.023," "0.011," and "0.045" instead of ".023," ".011," and ".045," respectively, for clarity and ease of reading.

II. Rejections under 35 U.S.C. section 112

A. 35 U.S.C. section 112 first paragraph

The Examiner has rejected claims 10, 11, 14, 15, and 19-40 under 35 U.S.C. section 112, first paragraph, on the grounds that these claims refer to a thrombin composition "free of fibrin clots" which the Examiner states is not supported by the specification. (Office Action, page 4, paragraph 8.)

These claims are supported by the specification. In using the processing set of the invention, plasma enters tubing 4 and is divided into a portion entering thrombin processing unit 40 and a portion entering clotting and adhesive proteins processing unit 60. The plasma entering unit 40 then enters mixing syringe 26. The ethanol and calcium chloride are then added to the mixing syringe. After agitation, the contents of the mixing syringe are transferred to the thrombin dispensing syringe 42, through filter 44. (Specification, pg. 13, lines 7-13; pg. 14, lines 1-19; pg. 15, lines 1-12; Figs. 1, 2 and 3.) The filter is "in the flow path between the mixing syringe 26 and the thrombin dispensing syringe 42." (Specification, pg. 15, lines 9-10.) "Particulate matter will be retained within the filter 44 prior to delivery of the thrombin to the dispensing syringe 42." (Specification, page 15, lines 11-12.) Thus, there are no particulates (e.g., fibrin clots) from the plasma in the thrombin that is present in the thrombin dispensing syringe. The claims, which refer to thrombin "free of fibrin clots", are supported by the specification. No new matter has been added.

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B. 35 U.S.C. section 112, second paragraph

The Examiner has rejected claims 22-25 and 34-37 under 35 U.S.C. section 112, second paragraph, on the grounds that the specification uses the term "clotting speed" which refers to a rate, when what is actually described is a clotting time. (Office Action, page 5, paragraph 10.) The Examiner correctly notes that the proper term is "clotting time." Applicants have amended claims 22-25 and 34-37 to refer to "clotting time" instead of "clotting speed." This is supported by the specification, which describes the time required to clot, not a rate of clotting. (See specification, page 9, line 9; page 10, line 4; page 16, lines 8, 13, and 23; and page 17, lines 2 and 9.)

Applicants have also amended the specification accordingly to change clotting "speed" to clotting "time." These amendments have been made to page 4, line 22; page 12, line 9; and page 17, lines 19 and 20.

In addition, applicants have corrected the title of Fig. 7 to change "clotting speed" to "clotting time" and Fig. 12 to add a label to the Y axis of "Clotting Time (Sec)". The omission of the label on the Y axis of Fig. 12 was an inadvertent omission in the submission of formal drawings, as Fig. 12 as originally submitted included this label.

The Examiner has rejected claims 26 and 38 under 25 U.S.C. section 112, second paragraph, on the grounds that the term "tangential relationship with a glass surface" is indefinite. (Office Action, page 5, paragraph 11.) Claims 26 and 38 have been amended to refer to a composition prepared in a glass container. This limitation is supported by the specification at page 11, lines 21-22; pages 16-19; and Fig. 7, which refers to glass containers.

III. Additional Amendment to Specification

Applicants have amended the specification to correct a typographical error on page 17, line 14. The word "conversation" in the phrase "conversation and activation" should be "conversion", as set forth in the specification at page 12, line 5, and in Fig. 11.

IV. Conclusion

In view of the foregoing, it is respectfully requested that the Examiner pass this case to issue. If the Examiner believes further issues remain outstanding or new ones

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have been generated, Applicants have formally requested an interview with the Examiner, prior to the Examiner's preparation of the response to this Amendment, to address and resolve those issues.

Date: July 19, 2005

Respectfully submitted,

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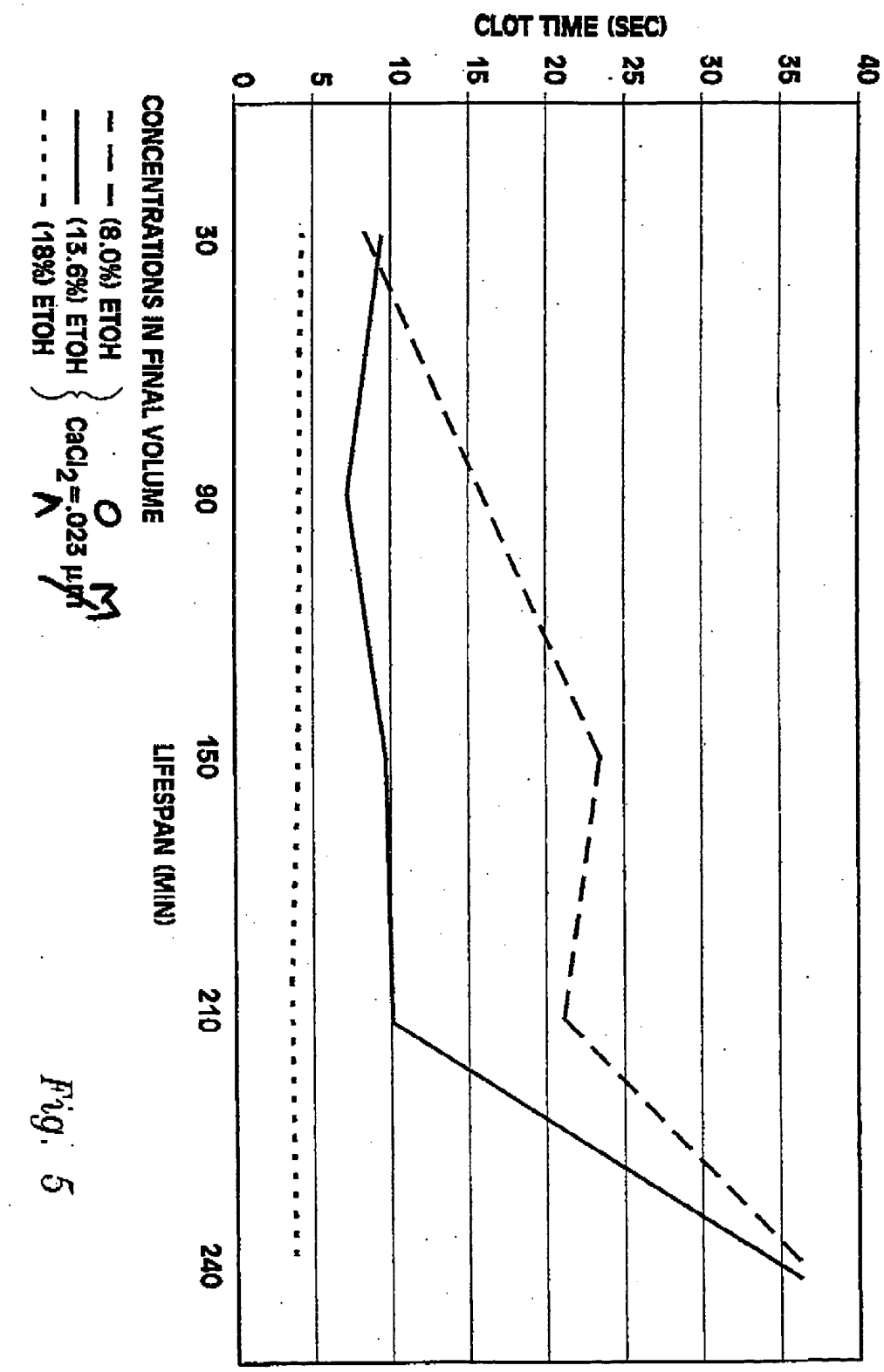

Fig. 5

Marked up drawing
Serial No. 09/709,237

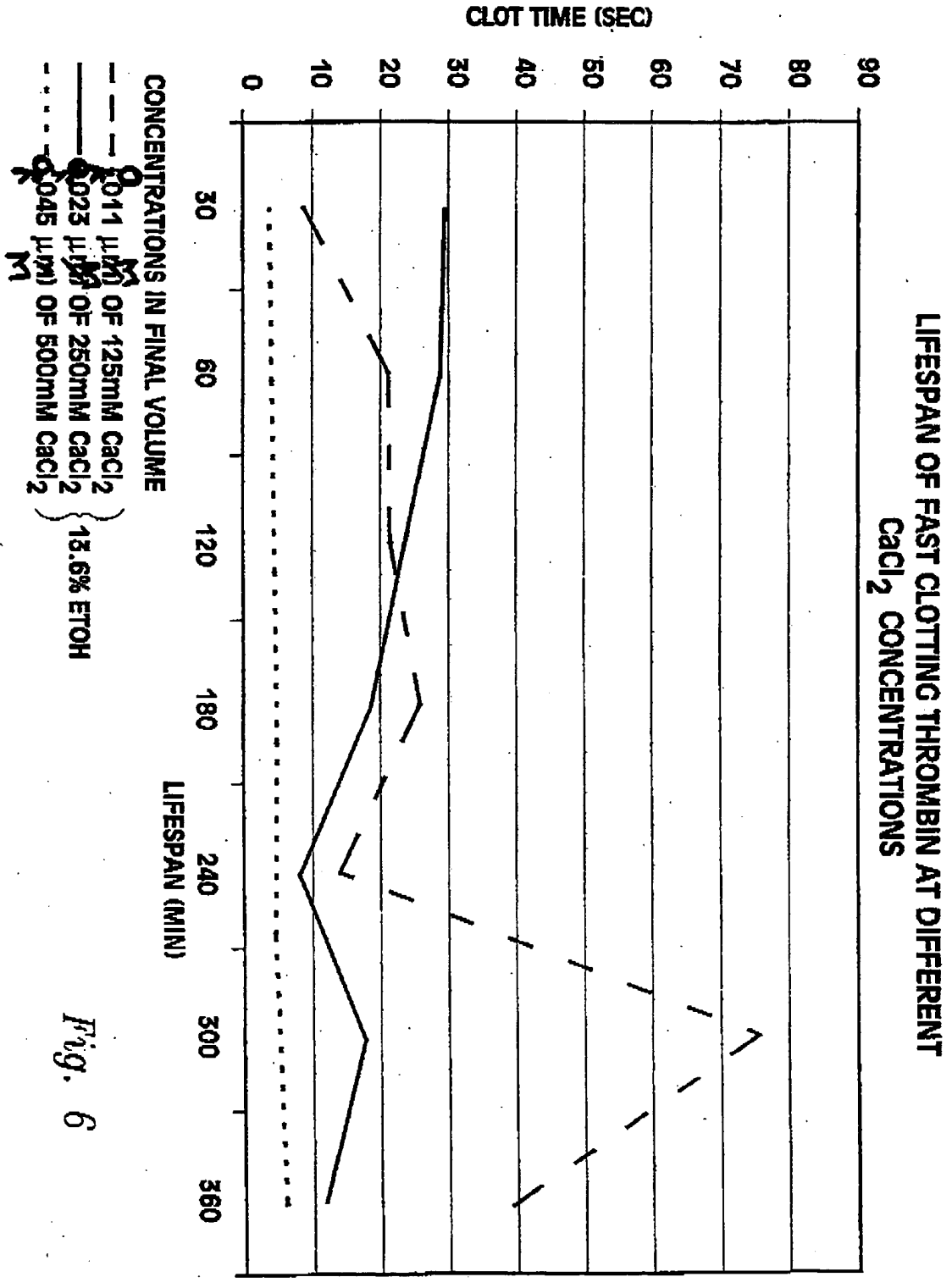

Fig. 6

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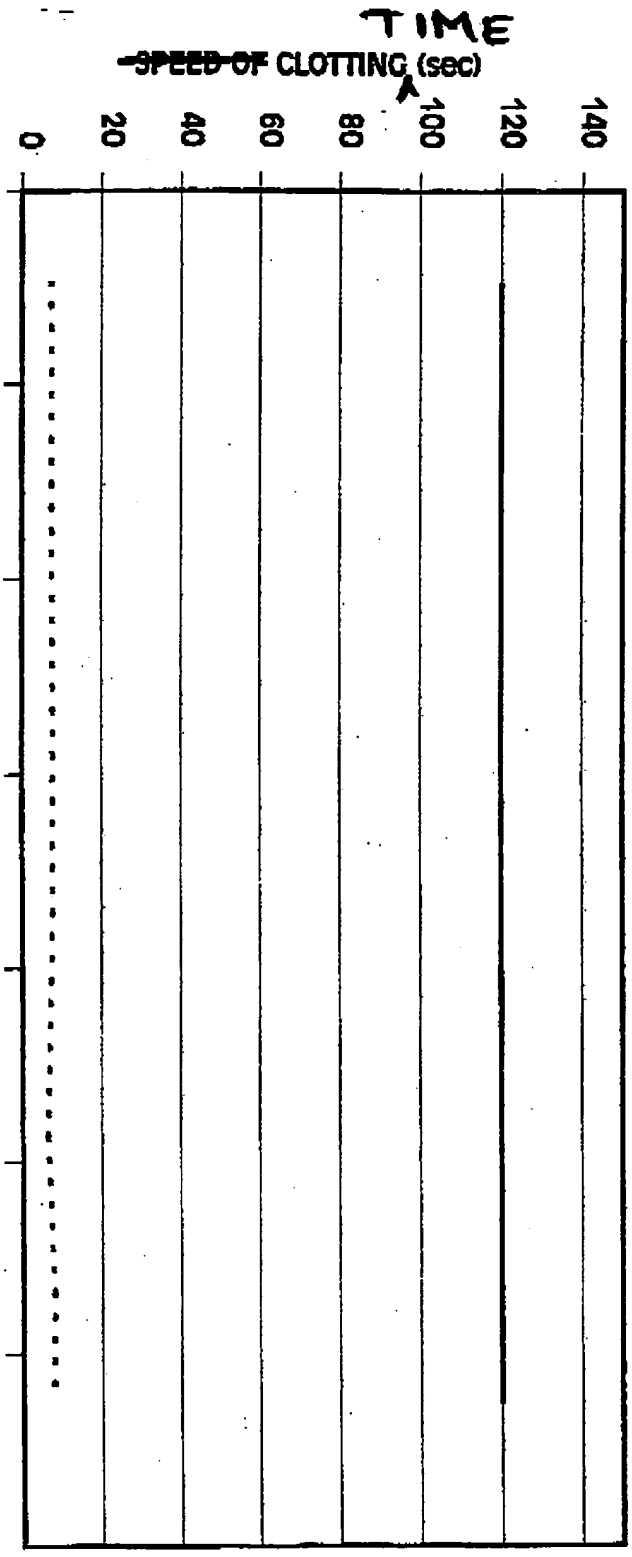

LIFESPAN AND CLOTTING TIME OF THROMBIN
PROCESSED IN CONTAINERS OF DIFFERENT MATERIALS

Fig. 7

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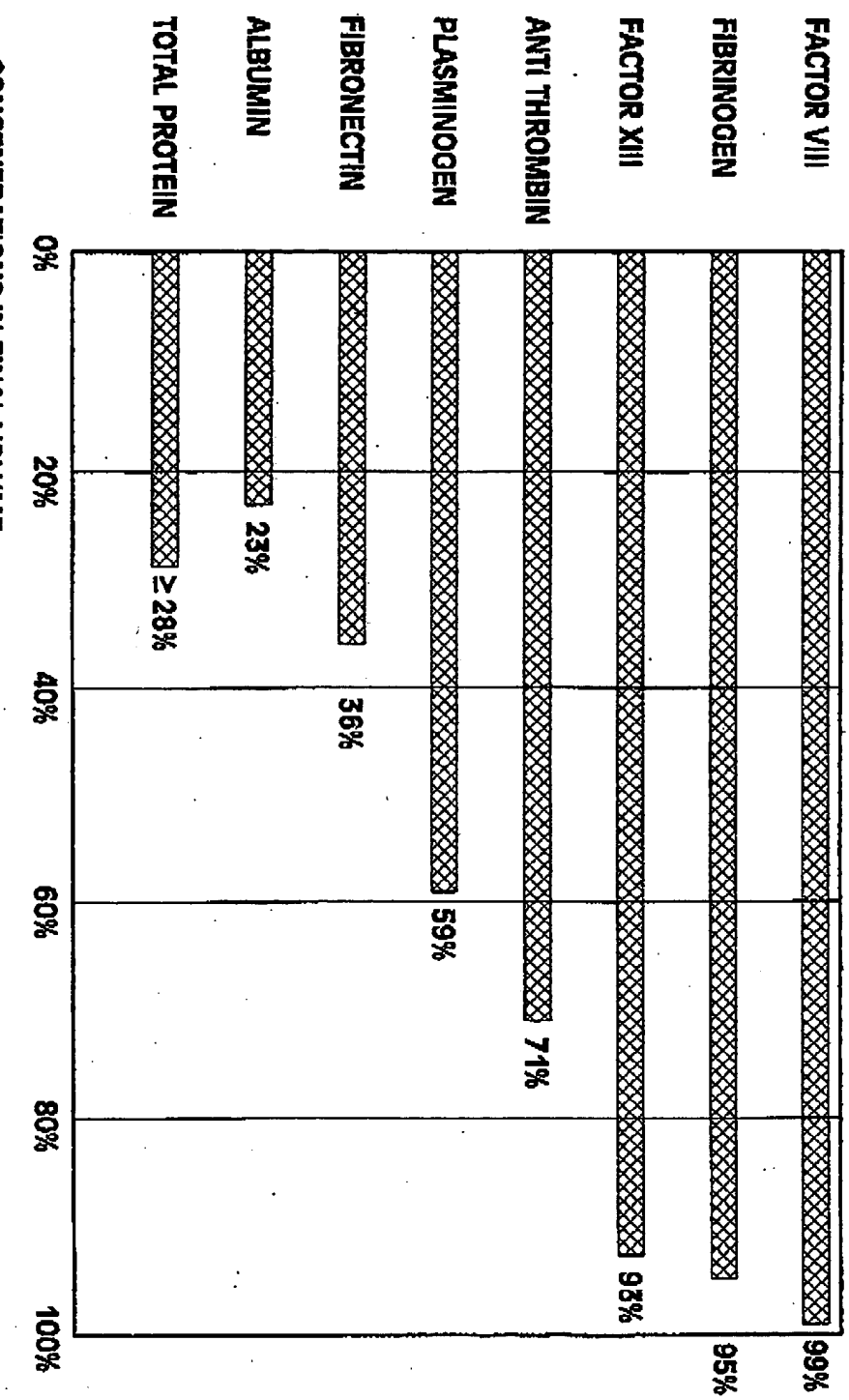

Fig. 8

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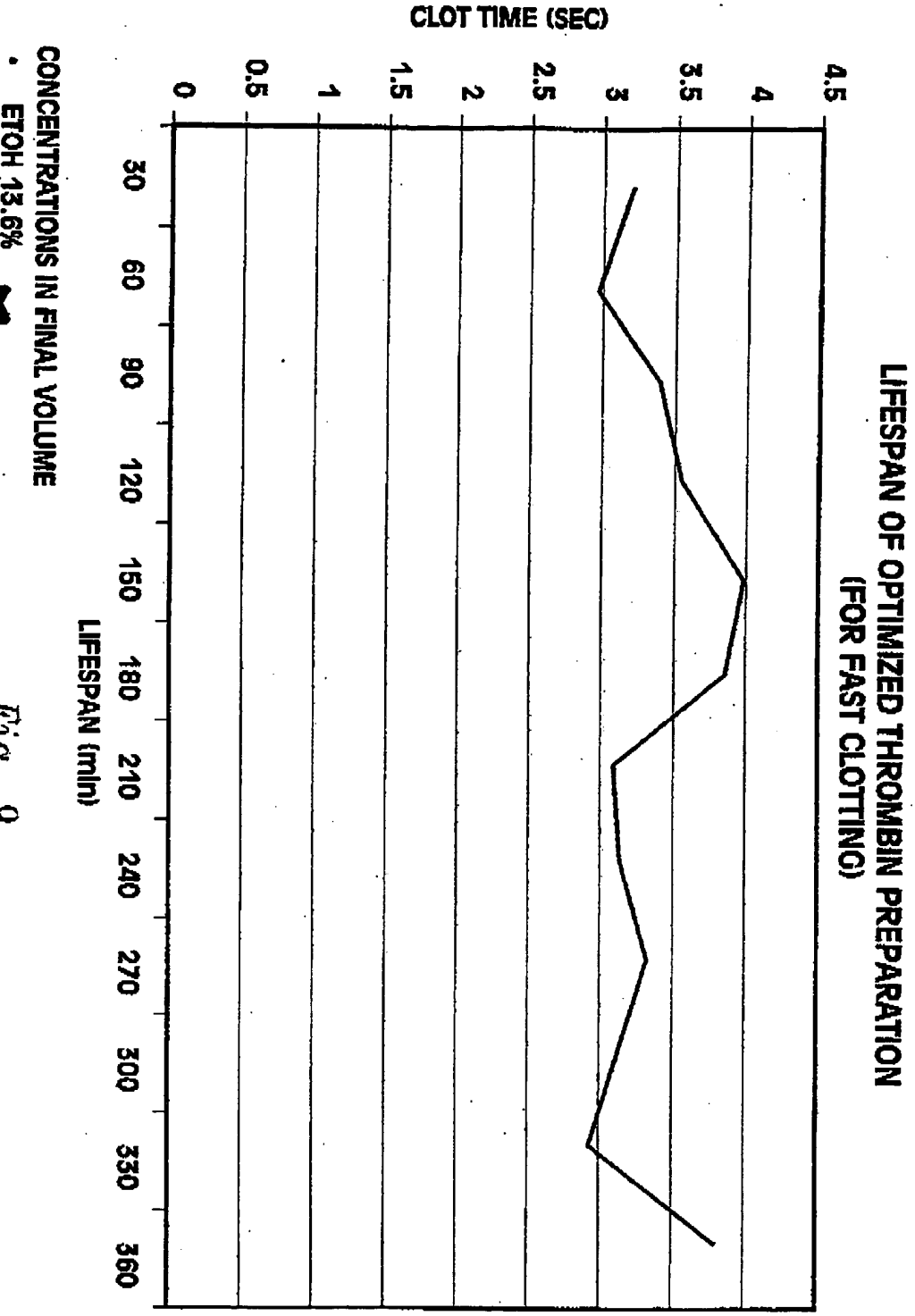

Fig. 9

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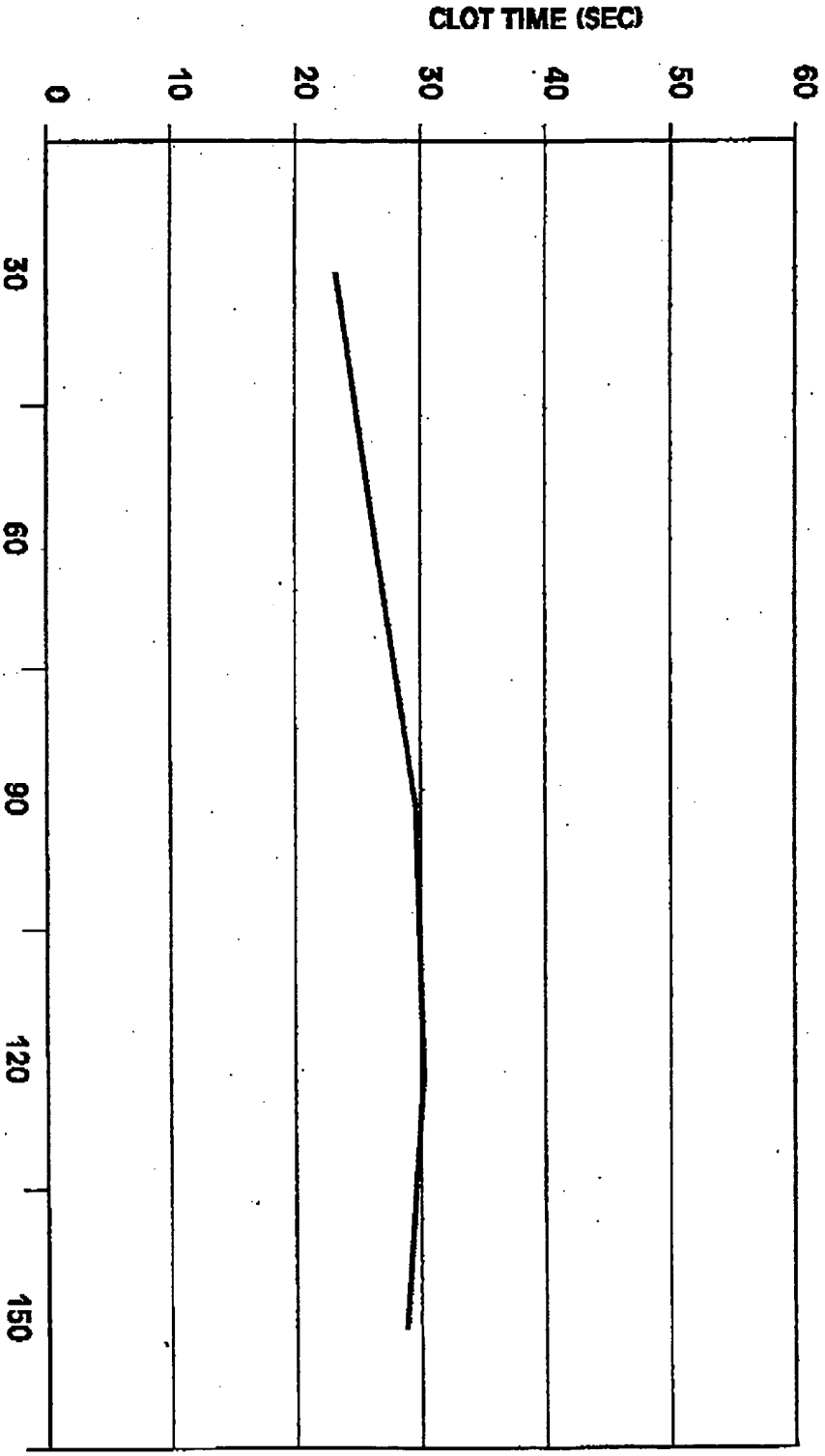

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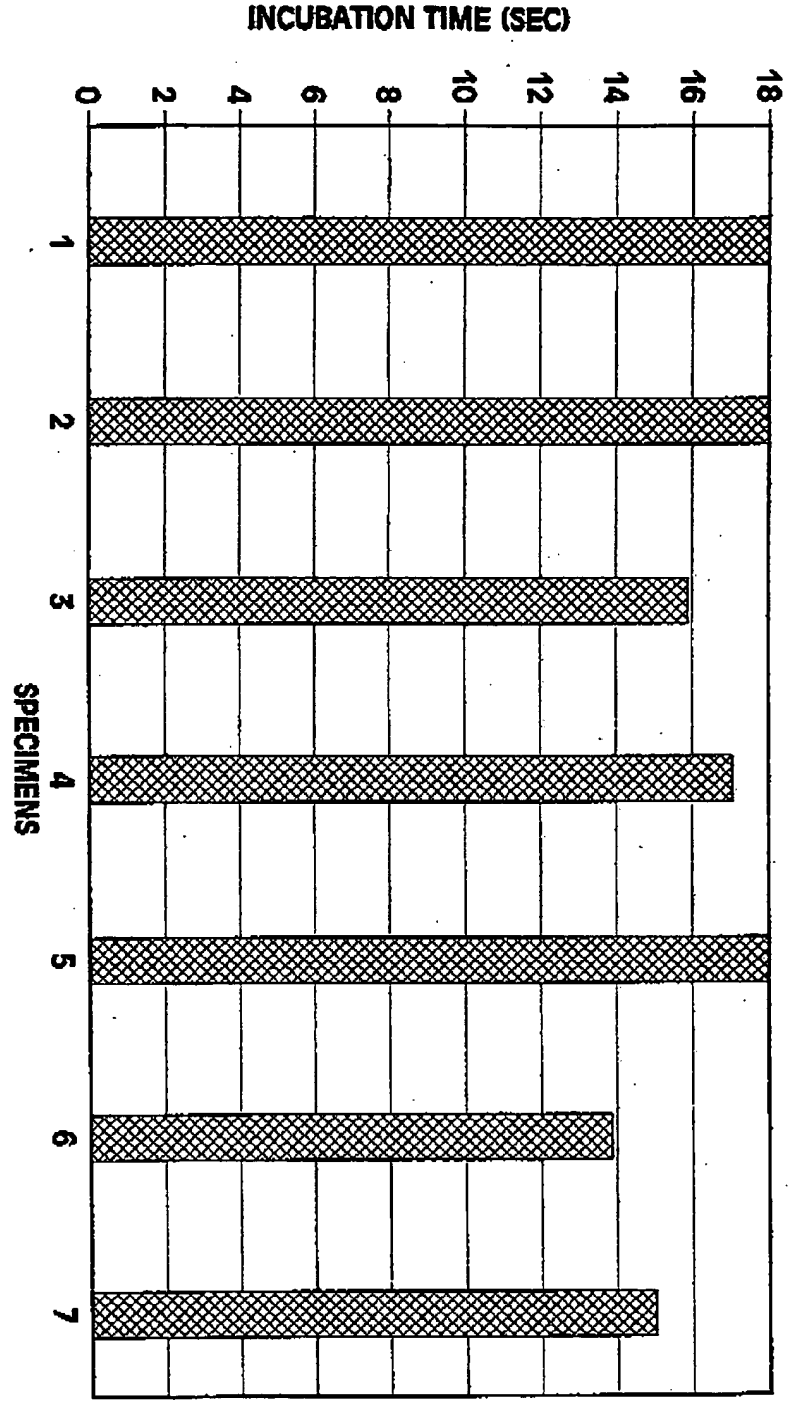
Fig. 10



TYPICAL CONVERSION/ACTIVATION PERIODS TO CONVERT OPTIMIZED, ENRICHED PROTHROMBIN FRACTION TO THROMBIN

CONCENTRATIONS IN FINAL VOLUME

- ETOH 13.6% M
- $CaCl_2$ .023 μM

Marked up drawing
Serial No. 09/709,237

Fig. 11

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